IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	**CRIMINAL NO._____**
	:	
v.	:	**DATE FILED: _____**
	:	
HAROLD F. FARBER, M.D., PC	:	**VIOLATIONS: 18 U.S.C. § 1001**
HAROLD F. FARBER, M.D.	:	**(false statements to the United States- 1**
	:	**count)**
	:	**21 U.S.C. § 844**
	:	**(illegal possession of controlled substances-**
	:	**1 count)**

INFORMATION

COUNT ONE

THE UNITED STATES ATTORNEY CHARGES THAT:

At times material to this information:

1. Defendant HAROLD F. FARBER, M.D., PC (FARBER PC) is a Pennsylvania professional corporation with offices located at 822 Montgomery Avenue, Narberth, PA 19072 and 9892 Bustleton Avenue, Philadelphia, PA 19115. The President, owner and sole shareholder of this professional corporation is defendant HAROLD F. FARBER, M.D.

2. Defendant HAROLD F. FARBER, M.D. (DR. FARBER) is a licensed physician specializing in dermatology.

THE DRUG STUDY

3. Actinic keratoses (AK) are generally regarded as premalignant precursors of squamous cell carcinoma that appear as dry, scaly lesions on skin chronically exposed to the sun.

4. Defendant DR. FARBER was a Principal Investigator (PI) on a clinical Phase III research study of a cream manufactured by 3M Pharmaceuticals to treat AK. A Phase III clinical

drug study reviews the efficacy and safety of an experimental drug product on human research participants. The study involving defendant DR. FARBER was titled "Vehicle-Controlled, Double-Blind Study to Assess the Safety and Efficacy of Imiquimod 5% Cream Applied Once Daily 2 Days per Week for the Treatment of Actinic Keratoses on the Head" (the drug study).

5. The drug study was approved by the Food and Drug Administration (FDA), which retained ultimate oversight authority of the study. As the PI in an FDA-approved drug study, defendant DR. FARBER had to comply with the drug study's protocols and FDA's requirements.

6. On or about July 5, 2001, and again on December 19, 2001, defendant DR. FARBER executed an FDA Form 1572 which provided the following commitments:

> I agree to conduct the study(ies) in accordance with the relevant current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights or welfare of subjects.
>
> I agree to personally conduct or supervise the described investigation(s).
>
> I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

7. Drug study participants were recruited and enrolled in the clinical study from defendant DR. FARBER'S medical practice. These patients' participation in the drug study was for 26 weeks, with 12 clinic visits required.

8. According to the drug study protocol, defendant DR. FARBER, as the PI and a qualified dermatologist, was to evaluate the safety and efficacy of the cream, including identifying any adverse events relating to administration of the experimental cream during the course of the clinical trial.

9. Defendant FARBER PC employed a clinical coordinator to enroll patients in this clinical research study. The clinical coordinator was not a physician, and was not qualified to identify AK lesions, or to perform safety assessments, local skin reaction assessments, and skin quality assessments on the clinical research participants in the drug study.

10. The clinical coordinator performed AK lesion identifications and assessments on a substantial proportion of drug study participants in violation of the drug study protocol.

11. Defendant FARBER PC, by its principals, agents, servants or employees, falsely represented that all of the clinical examinations were performed by defendant HAROLD F. FARBER, M.D., knowing that a substantial proportion of the required assessments had not been performed by a qualified dermatologist as mandated by the drug study protocol.

12. Defendant FARBER PC forwarded the results of the drug study to 3M Pharmaceuticals. Defendant FARBER PC was paid $89,500 for participating in the drug study.

13. Between in or about July 2001 and in or about November 2002, in Philadelphia, in the Eastern District of Pennsylvania, defendant

HAROLD F. FARBER, M.D., PC,

in a matter within the jurisdiction of the Food and Drug Administration, an agency of the executive branch of the United States, knowingly and willfully made materially false, fictitious, and fraudulent statements and representations in that defendant HAROLD F. FARBER, M.D., PC, submitted clinical examinations and assessments of drug study participants to the drug study sponsor that falsely represented that a qualified dermatologist had performed all of these clinical

assessments, when, as the defendant knew, a clinical coordinator who was not qualified to perform the clinical assessments had, in fact, done so.

In violation of Title 18, United States Code, Section 1001.

COUNT TWO

THE UNITED STATES ATTORNEY FURTHER CHARGES THAT:

1. The allegations contained in paragraphs 1 and 2 in Count One are incorporated here.

2. On or about October 30, 2002, in Narberth, in the Eastern District of Pennsylvania, defendant

HAROLD F. FARBER, M.D.

knowingly and intentionally possessed anabolic steroids, Schedule III controlled substances, without a lawful prescription and outside the course of his professional medical practice.

In violation of Title 21, United States Code, Section 844.

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PATRICK L. MEEHAN
UNITED STATES ATTORNEY